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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,308	10/24/2001	M. Parameswara Reddy	2058-181	8198

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PATENT LEGAL DEPARTMENT/A-42-C
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EXAMINER	
EPPERSON, JON D	
ART UNIT	PAPER NUMBER
1639	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/033,308	REDDY ET AL.	
	Examiner	Art Unit	
	Jon D. Epperson.	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-12,18,25,29,32-34 and 38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *38* is/are allowed.

6)☒ Claim(s) *1,5-12,18,25,29 and 32-34* is/are rejected.

7)☒ Claim(s) *12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/12/06; 5/5/04*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *10/20/2006*.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination (RCE)

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR.1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/27/06 has been entered. Claims 1, 2, 4-13, 15, 18, 20-25, 27, 29, 32-34 and 37 were pending. Claims 1, 12, 25, and 29 were amended. In addition, claim 38 was added and claims 2, 4, 13, 15, 20-24, 27 and 37 were canceled. Therefore, claims 1, 5-12, 18, 25, 29, 32-34, and 38 are examined on the merits.

Those sections of Title 35, US code, not included in the instant action can be found in previous office actions.

Withdrawn Objections/Rejections

2. The Jennissen et al. rejection is hereby withdrawn in view of Applicants' amendments to claims 1 and 12 adding the 1,2,4-carbonyl di-triazole limitation. The 35 U.S.C. § 112, second paragraph rejection denoted "A" is hereby withdrawn in view of Applicants' amendments to the claims removing the "consisting essentially of" language. The 35 U.S.C. § 112, first paragraph (new matter) rejection is hereby withdrawn in view of Applicants' amendments to the claims removing the "consisting essentially of" language. The Abbott rejection under 35 U.S.C. § 103(a) is hereby withdrawn in view of Applicants' amendments to the claims and the reasons set forth in the 10/27/06 response, page 14, last three paragraphs). The Jennissen et al./Stolowitz et

al. rejection is withdrawn in view of Applicants' amendments to the claims adding the cellulose, agarose, polypropylene, polystyrene, polymethacrylate, and nylon limitation for solid support materials. The Jennissen et al./Stolowitz et al./Milton/Okamoto/Guo rejection is also withdrawn in view of Applicants' arguments (e.g., see 10/27/06 Response, page 11, last four paragraphs).

New Rejections

Objections to the Claims

3. Claim 12 is objected to because of the following informalities:

A. Claim 12 as amended reads in part, "... being formed as a plate or film adapted for used in an assay." The Examiner recommends "for use" as a replacement.

Claims Rejections - 35 U.S.C. 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 5-12, 18, 25, and 32-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention. This is a new matter rejection.

A. The specification does not provide support for the current genus of "macromolecules" as set forth in independent claims 1 and 12. For example, the

specification only provides support for carbohydrates (e.g., see specification, paragraph 20, "Biological molecule as referred to herein encompasses ... carbohydrate [i.e., not macromolecular carbohydrates as currently claimed]"). Furthermore, to the extent that claim 12 reads on a larger set of molecular types than peptides, nucleic acids, etc. which are explicitly set forth in the specification (e.g., polystyrene) such scope also represents new matter. If applicant believes this rejection is in error, applicant must disclose where in the specification support for this amendment can be found in accordance with MPEP 714.02.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swenson et al. (Swenson et. al. "Novel Substitutions of Position 6 of LHRH Antagonist to Improve Potency and Safety" *Peptides: Chemistry, Structure and Biology* **1996**, *273*, 653-654) in view Stolowitz et al. (WO 87/06586) (Date of Publication is **November 5, 1987**) (of record) and Gasson et al. (WO 92/04353) (Date of Patent is **March 19, 1992**) as evidenced by Tripathi (e.g., Tripathi et al. Nucleic Acids Research **2004**, *33(13)*, 4345-4356) and Gehlsen (U.S. Patent Applic. No. US 2003/0091553 A1) (Publication Date is **May 15, 2003**).

For ***claim 29***, Swenson et al. (see entire document) teach a method of attaching a biological molecule to a solid support (e.g., see page 653, paragraphs 1 and 2 wherein an LHRH agonist decapeptide is attached to an MBHA resin). In addition, Swenson et al. disclose **(a)** providing a solid support having at least one available amino group the solid support being formed from a material selected from the group consisting of cellulose agarose polypropylene polystyrene polymethacrylate nylon (e.g., see page 653, paragraph 2 wherein MBHA is disclosed). Swenson et al. do not actually state that this resin is a polystyrene resin but the Examiner contends that this is an inherent property of the molecule or, alternatively, would be immediately envisioned as exemplified by Tripathi (e.g., see page 4347, column 1, first full paragraph defining MBHA resin as "polystyrene beads carrying [i.e., modified with] 4-mthyl benzhydrylamine"). Swenson et al. also disclose **(b)** reacting the available amino group on the solid support with an activating compound to form an activated support (e.g., see Swenson et al., page 653, paragraph 2, wherein 1,1'-carbonyldiimide is disclosed). Swenson et al. also disclose **(c)** providing a biological molecule wherein the biological molecule is selected from the group consisting

of hormones therapeutic drugs and drugs of abuse (e.g., see Table 1 wherein compound 11 containing "histamine" would qualify as a hormone and/or therapeutic drug). Swenson et al. do not explicitly state that histamine is a hormone and/or therapeutic drug but the Examiner contends that this is an inherent property of the molecule as evidenced by Gehlsen (e.g., see Gehlsen, abstract and description; see especially claim 5, wherein "histamine" is used for inhibiting and reducing reactive oxygen species (ROS)-mediated oxidative damage to hepatic cells). Finally, Swenson et al. also disclose **(d)** reacting the biological molecule with the activated support thereby covalently attaching the biological molecule to the solid support so that the biological molecule is available for use in an assay (e.g., see page 653, paragraph 2, "After removal of the Fmoc group the peptide-resin was treated first with 1,1'-carbonyldiimide [i.e., to form the activated resin] and then with the appropriate amine [i.e., the compounds listed in Table 1]"), which forms the requisite "urea" linkage.

The prior art teachings of Swenson et al. differ from the claimed invention as follows:

For ***claim 29***, Swenson et al. fail to teach an activating compound such as 1,2,4-carbonyl di-triazole. Swenson et al. only teach 1,1'-carbonyldiimide.

However, defg et al. teach the following limitations that are deficient in Swenson et al.:

For ***claim 29***, Stolowitz et al. disclose, for example, 1,2,4-carbonyl di-triazole as a coupling agent (e.g., see Stolowitz et al., page 10, paragraph 1, "A variety of azolides other ... may be employed ... include[ing] N,N'-carbonyldipyrazole, N,N'-carbonyldi-

1,2,3-triazole, N,N'-carbonyldi-1,2,4-triazole, N,N'-carbonyldiindole, N,N,-carbonylidibenzimidazole and N,N'-carbonyldibenztriazole and others"; see also Stolowitz et al., abstract; see also page 9, formula 7 wherein the urea linkage is shown; see also Summary of Invention, "In addition, a number of important specific objectives are also achieved using the present invention, including: The use of N,N'-carbonyldiimidazole for the activation of a chromatographic support with other than pendant hydroxyl groups; The preparation of a urea derivative of a bonded phase chromatographic support and the unique hydrophilic nature of the urea linkage"; see also Example 1, lines 8-18; see also page 3, lines 14-20; see also page 3, lines 21-26). Likewise, Gasson et al. also disclose carbonyl di-triazoles as standard coupling reagents that are "equivalent" to the cabonyldiimides disclosed in Swenson et al. (e.g., see Beecham et al., page 20, lines 25-35, "Other reactive N-acylating derivatives [that can be used include] ... a condensing agent such as a carbodiimide ... a suitable carbonyl compound, for example, N,N'-carbonyldiimidazole or N,N'-carbonylditriazole"

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to substitute the 1,2,4-carbonyl di-triazole coupling agent as disclosed by the combined teachings of Stolowitz et al. and Gasson to couple the compounds listed in Table 1 of Swenson et al. the immobilized peptide because all of these reagents are art recognized coupling agents (e.g., see Gasson, page 20, last paragraph; see also Stolowitz et al., page 10, paragraph 1, "A variety of azolides other than N,N'-carbonyl-diimidazole [i.e., the coupling agent used by Swenson] may be employed ... include[ing] N,N'-carbonyldipyrazole, N,N'-carbonyldi-1,2,3-triazole, N,N'-

carbonyldi-1,2,4-triazole, N,N'-carbonyldiindole, N,N,-carbonylidibenzimidazole and N,N'-carbonyldibenztriazole and others."). Furthermore, a person of skill in the art would have been motivated to use the triazole because Stolowitz et al., for example, state that they obtain "near quantitative derivatization of bonded supports ... by this synthetic route" (e.g., see Stolowitz et al., page 4, lines 29-30) and that their method is "versatile" because "almost [an] infinite variety of ligands ... can be employed as functionalizing reagents" (e.g., see Stolowitz et al., page 4, lines 34-35; see also Stolowitz et al., page 4, lines 23-25). In addition, Stolowitz et al. state that their coupling agents can be used to form "urea" linkages (e.g., see Stolowitz et al., page, 7, first full paragraph), which is exactly the same type of linkage that is being formed in Swenson et al. (e.g., see Swenson et al., page 653, paragraph 2, "we developed a method for making ureas"). Finally, a person of skill in the art would have reasonably expected to be successful because Stolowitz et al. shows the use of 1,2,4-carbonyl di-triazole in a coupling reaction involving amino groups to form ureas (e.g., see abstract; see also Summary of Invention; see also Examples). In addition, Stolowitz et al. also state, "almost [an] infinite variety of ligands ... can be employed as functionalizing reagents" (e.g., see Stolowitz et al., page 4, lines 34-35).

Alternatively, the Examiner contends that the combined references of Stolowitz et al. and Gannon stand for the proposition that a carbonyldiimide and 1,2,4-carbonyl di-triazole represent "equivalent" coupling reagents (e.g., see Gannon, page 20, last paragraph) and, as a result, motivation to substitute one for another need not be provided. See *in In re Fout*, 675 F.2d 297, 301, 213 USPQ 532, 536 (CCPA 1982) ("Express

suggestion to substitute one equivalent for another need not be present to render such substitution obvious").

Allowable Subject Matter

7. Claim 38 is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.
March 28, 2007

JON EPPERSON
PRIMARY EXAMINER